

Attorney Docket No.: P-4433-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): LEWKOWICZ, Shlomo et al. Examiner: Lamprecht, Joel
Serial No.: 10/536,982 Group Art Unit: 3737
Filed: May 31, 2005 Confirmation No.: 6340
Title: METHODS, DEVICE, AND SYSTEM FOR IN VIVO DIAGNOSIS

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RACHEL BENTOV UNDER 37 C.F.R. § 1.132

1. I was born in 1965 in Boston, Massachusetts.
2. In 1989, I was awarded the degree of Bachelors of Science in Biology from Tel Aviv University, in Tel Aviv, Israel. In 1996, I was awarded the degree of Masters of Science in Biochemistry from the Hebrew University, in Jerusalem, Israel.
3. I have been employed by Given Imaging Ltd. ("Given Imaging") of Yoqneam, Israel since April 2002, and currently hold the title Director of Intellectual Property. For four years prior to that, I was employed by the law firm EPLCZ and was outside counsel to Given Imaging on its intellectual property matters.
4. I am aware that the above-identified application, which is owned by Given Imaging, by way of an assignment from the inventors thereof, as recorded at the USPTO on May 31, 2005 at Reel 017106, Frame 0469, was filed in the United States Patent and Trademark Office ("USPTO") on May 31, 2005.
5. I am aware that the USPTO issued an Office Action on January 30, 2008 wherein the Examiner rejected all of pending claims 24-27, 29-31 and 35-37 under 35 U.S.C. § 102(c) as being anticipated by Madar et al. (U.S. Patent Application Publication No. 2004/0092825), published on May 13, 2004, which is after the earliest claimed priority date of Applicants' application, November 29, 2002, the filing date of U.S. Provisional Application No. 60/429,564. I understand that Madar et al. is available as a reference against

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Applicants' application under 35 U.S.C. § 102(e) because Madar et al. claim priority from U.S. Provisional Application No. 60/400,325, filed August 1, 2002, which is prior to November 29, 2002.

7. I submit this declaration on behalf of Given Imaging under 37 C.F.R. § 1.132 in support of a Declaration by Shlomo Lewkowicz under 37 C.F.R. § 1.131, which is being submitted to show that the subject matter of pending claims 24-27, 29-31 and 35-37 was conceived of by the inventors hereof prior to August 1, 2002.

8. As part of my responsibilities for Given Imaging during the relevant time period, I met regularly with Given Imaging scientists and technicians in an attempt to increase the value of the company. Part of this process involved reviewing with these scientists and technicians any new scientific techniques and discoveries that they have conceived in order to evaluate the commercial desirability to Given Imaging, the chances for patentability and the industrial applicability of these scientific techniques and discoveries. In so doing, I took detailed notes of my conversations and meetings with the scientists and technicians so as to keep a good record of these new scientific techniques and discoveries.

9. Prior to August 1, 2002, I met with Shlomo Lewkowicz, one of the inventors of this application, at the facilities of Given Imaging in Yoqneam, Israel, to discuss the elements and steps of certain discoveries and inventions of which he conceived, including those as subsequently filed in this patent application.

10. Attached hereto as Exhibit A are copies of two (2) pages from my notebook that reflect contemporaneous conversations that I had with Shlomo Lewkowicz on that day, wherein Shlomo Lewkowicz disclosed to me the elements of his invention as filed in this patent application. The two pages attached hereto are written mostly in the Hebrew language and partly in the English language.

11. Also attached hereto as Exhibit B is an English language translation that I prepared based upon the two notebook pages in Exhibit A. I state that I am fluent in both the Hebrew and English languages and am qualified to render this translation, and I believe that the translation of Exhibit A attached in Exhibit B is accurate.

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I declare under penalty of perjury that all statements made herein are based upon my own knowledge and believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of any patent that may be issued from the above-identified patent application.

Rachel Bentov
Rachel Bentov
Director of Intellectual Property
Given Imaging Ltd.

Date: July 30, 2008

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התקנת המצלמה

התקנת המצלמה נעשתה על ידי (שם) בחדר המדרגות
במסלול המדרגות המערבי.

Camera
התקנת המצלמה - imaging

EXHIBIT A

Chromoendoscopy –

Optical biopsy – optical methods to diagnose properties of a tissue.

Methods: color tissue, wash tissue, spray color and look to see what was absorbed. We don't have the option of spraying and we also can't wait a long time.

By us – combine color with a heavy molecule or a gel that is not absorbed by the stomach. Drink and after that swallow the capsule.

Colors [dyes]: methylene blue

Idodine (sic), congo red

Can use color in capsule that is dissolved in the small intestine.

large proteins and something that is not absorbed by the gut.

xxxxxxx

1) separation in time,
2) separation by wavelengths

Fluorescence – displasia (sic, dysplasia) – pre malignant cells

xxxxxxx

xxxxxxx

It is possible to image one frame with a light that does not cause fluorescence

and immediately green
after that --- nylon
-- subtract overlays
the images
one from the other
(image subtraction) ---
can see the results of
fluorescence

autofluorescence

- Capability of illuminating with discrete wave lengths and high energy pulses
- Light detector of a specific range with a filter

- Regular image alternating with fluorescent image, perform a superimposition of the images
- Swallow two capsules together
- If the capsule has image processing [capabilities], it will be possible, based on initial identification, to illuminate the identified spot with a pulse of fluorescent light.

photodynamic
diagnostics is
being done in
endoscopy

ALA (long acid) – is selectively absorbed by cancerous cells
today it is used in photodynamic therapy. It absorbs light and burns the cell it is in

It is possible to swallow more than others

Peak time of
4-6 [hours]

If you illuminate in 400nm this material will return light in 600-800 [nm]

4-6 hours pass – and then there are a few hours in which ALA returns light

- Radioactive material -

The capsule contains a compartment into which radioactive material can be inserted and the subject is imaged by a gamma camera

- the combination with the imaging-